

# PATENT COOPERATION TREATY

From the:  
INTERNATIONAL SEARCHING AUTHORITY

To:

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## PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing **14 MAR 2005**  
(day/month/year)

Applicant's or agent's file reference

**DGC DAA 02 1377 1495**

**FOR FURTHER ACTION**

See paragraph 2 below

International application No.

**PCT/AU2004/001699**

International filing date (day/month/year)

**2 December 2004**

Priority date (day/month/year)

**2 December 2003**

International Patent Classification (IPC) or both national classification and IPC

**Int. Cl. 7 A01H 5/00**

Applicant

**JOHNSON & JOHNSON RESEARCH PTY LIMITED et al**

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

**DATA ENTERED**  
**11 18.3.05**

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the IPEA/AU

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WRITTEN OPINION OF THE  
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International application No.

PCT/AU2004/001699

## Box No. I Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

## a. type of material

- ☒ a sequence listing  
☐ table(s) related to the sequence listing

## b. format of material

- ☐ in written format  
☒ in computer readable form

## c. time of filing/furnishing

- ☐ contained in the international application as filed.  
☐ filed together with the international application in computer readable form.  
☒ furnished subsequently to this Authority for the purposes of search.

3. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

## 4. Additional comments:

The original disk containing the sequences was found to be damaged prior to a sequence search being carried out. A substitute disk was filed on 24 February 2005 along with a statement that "the information recorded in computer readable form [i.e. on the substitute disk] is identical to the written sequence".

**WRITTEN OPINION OF THE  
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International application No.

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**Box No. V** Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

**1. Statement**

Novelty (N)	Claims 1-97	YES
	Claims	NO
Inventive step (IS)	Claims 1-97	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-97	YES
	Claims	NO

**2. Citations and explanations:**

The following citations, first raised in the corresponding International Search Report, are referred to as follows:

D1 – WO 1999011765  
D2 – WO 1999035902

The invention the subject of the present international application resides in a cytochrome P-450 reductase enzyme from a poppy plant characterised in that it is involved in alkaloid biosynthesis and which inhibits the accumulation of at least one benzylisoquinoline alkaloid (such as (S)-reticuline) above a normal level of the alkaloid in the plant (that is, this reductase catalyses (S)-reticuline in a biosynthetic pathway). By controlling the expression of this reductase (encoded by the gene CPR2) in a poppy plant, the alkaloid profile as well as the total alkaloid yield can be controlled.

Clearly the most relevant art is D1. This patent, the work of the present applicants, also relates to a cytochrome P-450 reductase from poppy plants. This reductase does not appear to be involved in the catalysis of benzylisoquinoline alkaloids (such as (S)-reticuline. Further, SEQ ID NO: 1 from the present application and the sequence shown in Figure 9 (in D1) only possess an 83% identity.

D2 relates to a mutagenized poppy plant which produces (S)-reticuline in higher than normal quantities.

Hence, neither D1 nor D2 are considered prejudicial to the novelty of claims 1-97. Finally, there does not appear to be reason to suspect a skilled person could use the teachings of D1 or D2 to determine the particular cytochrome P-450 reductase characterised by the present application. Hence the claims are considered to involve an inventive step.

**WRITTEN OPINION OF THE  
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International application No.

**PCT/AU2004/001699**

**Box No. VIII** Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The claims of the international application, in general, are not fully supported by the description. Independent claims 1, 12, 36, 50, 62 and 87 relate to any cytochrome P-450 enzyme (as well as nucleic acid molecules encoding therefore etc) whereas there seems to only be support for the gene CPR2 (as shown in SEQ ID NO: 1) which encodes a particular cytochrome P-450 reductase. Because claims 1, 12, 36, 50, 62 and 87 are not limited to CPR2 these claims are not considered to be fully supported by the description.